

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
11133z

Re Application Of: B. Tjellstrom, et al.

Serial No.
09/925,671

Filing Date
August 9, 2001

Examiner
J. H. Roark

Group Art Unit
1644

Title: ORAL IMMUNOGLOBULIN TREATMENT FOR INFLAMMATORY BOWEL DISEASE

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Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231

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37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

OR

☐ the fee set forth in 37 CFR 1.17(p).

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Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. 19-3886/RCT as described below. A duplicate copy of this sheet is enclosed.
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Janet Grossman

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Dated: March 10, 2003

Peter I. Bernstein

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: B. Tjellstrom, et al. **Examiner:** J. H. Roark
Serial No.: 09/925,671 **Art Unit:** 1644
Filing Date: August 9, 2001 **Docket:** 11133z
For: ORAL IMMUNOGLOBULIN **Date:** March 10, 2003
TREATMENT FOR INFLAMMATORY
BOWEL DISEASE

Commissioner for Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

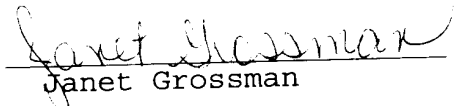
In accordance with 37 C.F.R. §§1.97 and 1.98, it is requested that the following disclosures, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. Canva-Delcambre, V., et al. (1996) "Treatment of severe Crohn's disease with anti-CD4 monoclonal antibody" *Aliment Pharmacol Ther.* 10:721-727;
2. Chang, L., et al. Combining therapies for IBS" *IM*, February 1994, pp. 27-34;
3. Eibl, M.M., et al. (1988) "Prevention of Necrotizing enterocolitis in low-birth-weight infants by IgA-igG Feeding" *The New England Journal of Medicine* 319(1):1-7;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

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Dated: March 10, 2003


Janet Grossman

4. Griffiths, A.M., et al. (1995) "Meta-analysis of Etenar Nutrition as a Primary Treatment of Active Crohn's Disease" *Gastroenterology* 108:1056-1067;
5. Hanauer, S.B. (1996) "Inflammatory Bowel Disease" *Drug Therapy* 334(13):841-848;
6. Haque, K.N., et al. (1995) "Comparison of two types of intravenous immunoglobulins in the treatment of neonatal sepsis" *Clin Exp Immunol* 101:328-333;
7. Knoflach, P., et al. (1990) "Crohn Disease and Intravenous Immunoglobulin G" *Annals of Internal Medicine* 112(5): 385-386;
8. Korelitz, B.I., et al. (1996) "A History of Immunosuppressive Drugs in the Treatment of Inflammatory Bowel Disease: Origins at the Mount Sinai Hospital" *The Mount Sinai Journal of Medicine* 63(3 & 4):191-201;
9. Levine, D.S., et al. (1992) "Intravenous Immunoglobulin Therapy for Active, Extensive, and Medically Refractory Idiopathic Ulcerative or Crohn's Colitis" *The American Journal of Gastroenterology* 87(1):91-100;
10. Löfberg, R. (1997) "Medical treatment for inflammatory bowel disease - refinements and new modalities" *Journal of Internal Medicine* 241: 1-4;
11. Prantera, C., et al. (1996) "An Antibiotic Regimen for the Treatment of Active Crohn's Disease: A Randomized, Controlled Clinical Trial of Metronidazole plus Ciprofloxacin" *The American Journal of Gastroenterology* 91(2):328-332;
12. Sandborn, W.J. (1996) "A Review of Immune Modifier Therapy for Inflammatory Bowel Disease: Azathioprine, 6-Mercaptopurine, Cyclosporine, and Methotrexate" *The American Journal of Gastroenterology* 91(3):423-432;
13. Schmidt, Ch., "7S-Immunoglobulins in the Treatment of Crohn's Disease" *Klinikerzt* 19(11):558;

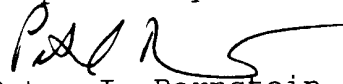
14. Sutherland, L.R. (1997) "Maintenance Therapy for Inflammatory Bowel Disease: What Really Works" *Can J Gastroenterol* 11(3):261-264;
15. Tjellström, B., et al. (1993) "Oral immunoglobulin A supplement in treatment of *Clostridium difficile* enteritis" *The Lancet* 341:701-702;
16. Tjellström, B., et al. (1997) "Oral immunoglobulin treatment in Crohn's disease" *Acta Pædiatr* 86:221-223;
17. Wolff, A.G., et al. (1988) "Treatment of Morbus Crohn with Intravenous Immunoglobulin" *Moalsschr Kinderheilkd* 136:101; and
18. U.S. Patent No. 4,477,432, issued October 16, 1984.

Pursuant to 37 C.F.R. §1.98(d), copies of publications are not provided, as these references were previously submitted to the Examiner in connection with the parent case, Serial Number 09/247,396, filed on February 10, 1999.

Consideration of this Information Disclosure Statement is respectfully requested, since the art provided may be material to the examination of the present application as defined under 37 C.F.R. §1.56.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,


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